

**REMARKS**

With entry of this amendment, claims 15-16 and 19-29 are pending in this application. Claims 15, 19 and 20 are amended. Claims 17 and 18 are cancelled. Claims 28 and 29 are newly added.

The amendments to the claims and the newly added claims are believed to be fully supported by the specification, including specifically at pages 9, 13, 17, and the claims as originally filed. No new matter is believed to be introduced by the above amendments.

Reconsideration of this application, as amended, is respectfully requested.

**The Information Disclosure Statement**

Applicant's Information Disclosure Statement dated March 6, 2002 was objected to for the reasons below. Applicants respond to the various objections in the order in which they are raised in the pending Office Action.

Document B4 (WO 97/09996) was objected to as not being in English. Applicant notes that US Patent No. 6,333,306 B1, over which the instant application is rejected on the basis of double patenting, is in English and derives its priority from WO 97/09996. As the '306 patent is already of record, applicant will thus not resubmit this document in an updated Information Disclosure Statement.

Applicant is attempting to obtain an English language counterpart/abstract of document C2 (Wick et al., 1996) and will provide it as soon as it is available.

Documents C9 (Beyermann et al.) and C10 (Goodnough et al.) listed in Applicant's IDS are being resubmitted in an updated IDS.

### Objections to the Specification

The specification was objected to because of various informalities and misspelling. Consistent with the Examiner's requests, Applicant amended the specification as follows:

On page 2, first paragraph, third line; page 3, third paragraph, line 5; page 4, second paragraph, line 7; page 6, second paragraph, lines 1 and 3; page 8, first paragraph, lines 4 and 6; and page 15, second paragraph, line 13 (two incidents), the abbreviation "ca.", which stands for "circa", was replaced with "about".

On page 5, second paragraph, line 3, "20 %" was replaced with "20%".

Similarly, on page 8, first paragraph, "20 %" on line 4 was replaced with "20%", "30 %" on line 5 was replaced with "30%", and "10 %" on line 8 was replaced with "10%".

On page 9, second paragraph, line 6, "ifon" was replaced by "iron". In the third paragraph, line 4, "ar" was replaced by "are".

On page 10, second paragraph, line 11, "and" was added before "calcium pantothenate" and "etc" was deleted.

On page 12, second paragraph, line 8, "\_ons" was replaced by "ions".

On page 14, second paragraph, line 9, "lyophili\_ate" was replaced by "lyophilate". On the fourth paragraph, line 8, "born" was replaced by "kept".

On page 16, first paragraph, line 10, ",etc." was deleted. In the second paragraph, line 5, "\_100,000" is replaced by "100,000".

On page 22, first paragraph, third line, "in\_order" is replaced by "in order".

The revisions to the specification are minor corrections that are not substantive.

In addition, the Abstract is objected to as being two paragraphs. A new, one paragraph Abstract is submitted with this amendment.

The foregoing amendments to the specification are believed to overcome the pending objections to the various recited alleged informalities.

The claims are amended as follows:

Claim 15 is amended, *inter alia*, to include some of the limitations of claim 17 and to refer to an amount of erythropoietin from about 250 U to less than about 2,000 U.

Claims 17 and 18 are cancelled.

Claim 19 was amended merely to clarify the language.

Claim 20 was amended to refer to amount of erythropoietin from about 1,000 U to less than about 2,000 U.

Claims 28 and 29 are newly added.

The foregoing amendments to the claims are fully supported by the specification and are not believed to present new subject matter.

### The Section 112 Claim Rejections

Claims 15-27 stand rejected under 35 USC § 112, second paragraph, as being indefinite for the reasons detailed below. Applicants address each of these technical rejections below.

Claims 15-27 are rejected due to use of the symbol "U" as a unit of measurement. This rejection is traversed. One skilled in the art to which the current application is directed would understand the symbol "U" to stand for "amu," which is a unit of mass used by chemists and physicists for measuring the mass of atoms and molecules. Specifically, an amu, or "u," equals  $1.6605402 \times 10^{-27}$  kilograms (kg). Applicants' submit herewith a copy of the definition of this term that is afforded in the IUPAC Compendium of Chemical Terminology, 2<sup>nd</sup> Edition (1997), as well as page F-70 of the CRC, 64<sup>th</sup> Edition, providing this standard definition. Reference is also made to US Pat. No. 6,333,306 B1, which is a part of the record.

Analogously, claim 24 is rejected as being indefinite for use of the symbol "D" in referring to the molecular weight of the iron complex. This rejection is also traversed. One skilled in the art to which the current application is directed would understand that the symbol D (or sometimes Da) is the atomic mass unit known as a Dalton. The Dalton is often used in microbiology and biochemistry to state the mass of large organic molecules. Applicants' submit herewith a copy of the definition of this term that is afforded in the IUPAC Compendium of Chemical Terminology, 2<sup>nd</sup> Edition (1997). This unit of measurement has also been used to measure the atomic mass of iron complexes. See, e.g., Geisser et al, *Arzneimittel Forschung* 42(II), No. 12, (1992) pp.1439-1452, particularly table 2 on page 1442 (copy enclosed).

For the foregoing reasons, the Section 112 rejections are traversed and these rejections should be withdrawn.

#### The Double Patenting Rejections

Claims 15-27 stand rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of US. Pat. No. 6,333,306 in view of Mercuriali and Ihghilleri. This rejection is traversed.

As amended, applicants claims are directed to methods of treating disturbances in iron metabolism in a patient undergoing heaemodialysis or treatment for anemia comprising administration of low doses, that is less than about 2,000 U, of active erythropoietin. Doses less than about 2,000 U erythropoietin are not contemplated in or covered by the '306 patent. Thus, the pending claims, as amended, are patentably distinct over US. Pat. No. 6,333,306 and the double patenting rejection should be withdrawn.

#### Conclusion

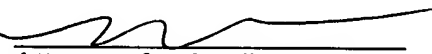
In view of the foregoing amendments and arguments, applicants respectfully submit that all pending claims are in condition for allowance and solicit early allowance of this case.

Serial No. 10/047,749  
Filed: October 23, 2001

A one-month extension fee of \$110.00 is due with the filing of this amendment. Applicants submit herewith a fee sheet authorizing the Patent Office to charge applicants' Deposit Account 08-2525 accordingly.

In addition, should the Patent Office determine that any other fee is due, the Commissioner is hereby authorized to charge payment of any additional fees associated with this communication to Deposit Account No. 08-2525.

Respectfully submitted,



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Enclosures

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